

## **Fiscal Note for addition to rule for North Carolina Division of Public Health Requires OSBM Review**

**Agency:** Dept. Of Health and Human Services, Division of Public Health, Epidemiology Section, Communicable Disease Branch

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**Rule Citations:** 10A NCAC 41A .0214

**Purpose of Addition :** Provide control measures for Hepatitis C virus infection.

**Relevant Statutes:** GS 130A–135; 130A–144

**State Impact:** Yes

**Local Impact:** Yes

**Substantial Economic Impact:** No

**Significant Rule Change:** No

### Reason for Fiscal Note

The addition of these control measures requires a fiscal note because they would require communicable disease staff at local health departments to expend time locating and notifying persons who have been identified by persons with acute hepatitis C virus (HCV) infection as needle-sharing partners. Persons newly infected with HCV are usually asymptomatic, so acute HCV infection is rarely identified or reported. During 2005–2009, the average number of acute HCV infections reported to the NC Division of Public Health each year was 27. Given the low number of cases reported annually, it is estimated that local health department staff time required to locate and notify needle-sharing partners will be minimal. The impact on Communicable Disease Branch staff is also estimated to be minimal, since location and notification of needle-sharing partners will be conducted by local health department staff.

The addition of these control measures should have no measurable fiscal impact on physicians, other healthcare providers, or healthcare facilities, since the control measures specified for physicians are consistent with the current standard of medical care and current treatment guidelines published by the Centers for Disease Control and Prevention (*Sexually Transmitted Disease Treatment Guidelines*, MMWR, Vol. 59, No RR-12, December 17, 2010), which are incorporated by reference in 10A NCAC 41A .0201.

The addition of this control measure should also have no measurable fiscal impact on healthcare providers in the state who perform invasive procedures, since these providers are currently required to follow Centers for Disease Control and Prevention recommendations regarding blood and body fluid precautions, as incorporated by reference in 10A NCAC 41A.0201. (See also 10A NCAC 41A .0206, Infection Prevention-Health Care Settings).

Finally, no measurable fiscal impact is anticipated in association with paragraph (1)(B) (“Infected persons shall... not donate or sell blood, plasma, platelets, or other blood products”). In the US, each donation center manages its own facility, but all must operate within regulatory guidelines established by the FDA, which require that plasma donors submit to a pre-donation physical exam to include medical history questions and tests for transmissible viruses. (Standards for determining the suitability of a donor can be found in the FDA Code of Federal Regulations, 21CFR640.3.) A minimal financial benefit might be realized by blood banks or other organizations that collect blood products if fewer HCV-infected persons attempt to donate or sell blood products.

### **North Carolina Communicable Disease Branch**

The Communicable Disease Branch is located within the Epidemiology Section of the Division of Public Health. The goal of the Communicable Disease Branch is to conduct surveillance activities for communicable diseases, including HIV and other STDs, and other diseases reportable under NC law, and to protect the health of the citizens of North Carolina through prevention and control of those diseases. Branch staff review case report data and provide consultation and assistance to local health directors and others to investigate disease cases and outbreaks, determine appropriate controls measures to help prevent disease transmission, and ensure that these control measures are applied. The Branch is also responsible for monitoring health data from hospital emergency departments, poison center calls, ambulance data, and

other sources to detect diseases that may result from terrorism and for providing situational awareness during disease outbreaks, natural disasters, or man-made disasters. In addition, the AIDS care component of the Branch ensures that HIV/AIDS-infected individuals are able to access a continuum of care services, including case management, medical and dental care, complicated and expensive medications regimens, housing, and a full range of ancillary services.

*Proposed Rule 10A NCAC 41A .0214 Control Measures-HCV*

Hepatitis C virus (HCV) is the most common bloodborne infection in the United States. HCV infections can lead to chronic liver disease and are therefore pose a major public health problem. Control measures for HCV, when correctly implemented, can decrease the risk of disease transmission and reduce the risk of chronic liver disease. Early detection is important for preventing transmission from newly infected persons. In addition, recent studies suggest that treatment within the first 6 months following HCV infection can produce a sustained virologic response rate of 85% or higher.

HCV is most efficiently transmitted through large or repeated percutaneous exposure to infected blood- e.g., through transfusion of blood from unscreened donors or through use of injecting drugs. Although much less frequent, occupational, perinatal, and sexual exposures also can result in transmission of HCV. Sixty to 70% of persons newly infected with HCV are asymptomatic and the majority of infected persons are not aware of their infection because they are not clinically ill. However, infected persons serve as a source of transmission to others and are at risk for chronic liver disease and other HCV-related complications that can occur.

The delivery of health care has the potential to transmit HCV to both health care workers and patients. Outbreaks of HCV infection have occurred in outpatient settings, hemodialysis units, ambulatory surgery facilities, and hospitals. CDC researchers reviewing hepatitis B and hepatitis C outbreaks reported between June 1998 and June 2008 identified 15 hepatitis C outbreaks in non-hospital healthcare settings. In all of these outbreaks, investigators uncovered significant breaches in basic infection control principles, such as reuse of syringes or lancing devices, contamination of medication vials by reuse for multiple patients, and lapses in hand hygiene. North Carolina experienced its own hepatitis C outbreak in 2007–2008 when 1,200 patients were potentially exposed due to infection control lapses at a cardiology clinic.

If compliance with this rule is achieved, there is a potential for cost savings to be incurred from early detection and treatment of HCV infections resulting in a lower incidence of chronic infections and complications. It is difficult to estimate the magnitude of these savings, however, given the wide variability in treatment options and responses to treatment, as well as the difficulty of predicting how many persons with HCV infection would be diagnosed earlier if compliance with this rule were achieved.

The total estimated fiscal impact of the addition of HCV control measures is shown below.

<b>NC DPH Addition of HCV Control Measures</b>	
<b>Impact Analysis</b>	
<b>Impact on CD staff in Local Health Departments (LHD)</b>	
Total number of confirmed cases of acute HCV per year <sup>1</sup>	27
Total number of confirmed cases reporting injection drug use per year <sup>2</sup>	16
Estimated number of needle-sharing partners identified per confirmed case reporting injection drug use <sup>3</sup>	3
Total number of needle-sharing partners requiring notification by LHD per year	48
Estimated time (hours) required to locate and notify each needle-sharing partners (per needle-sharing partner)	2
Total time (hours) required for location and notification of all needle-sharing partners	96
Total LHD Registered Nurse (RN) cost (average hourly wage of \$19.59 times 96 hours) <sup>4</sup>	\$ 1,881
<b>Collective total cost to local health departments</b>	<b>\$ 1,881</b>

<b>Impact on CD staff in NC Communicable Disease Branch</b>	
Total number of confirmed cases of acute HCV per year <sup>5</sup>	27
Total number of confirmed cases reporting injection drug use per year <sup>2</sup>	16
Estimated number of needle-sharing partners identified per confirmed case reporting injection drug use <sup>3</sup>	3
Total number of needle-sharing partners requiring notification by LHD per year	48
Estimated time (hours) required to consult with local health department staff regarding location and notification of each needle-sharing partner (per needle-sharing partner)	0.25
Total time (hours) required to consult with local health department staff regarding location and notification of all needle-sharing partners	12
Total state RN/Subject matter expert (SME) cost (hourly wage of \$33/hr times 12 hours) <sup>6</sup>	\$ 396
<b>Total cost to state NC Communicable Disease Branch</b>	<b>\$ 396</b>
<b>Total Costs from Rule Change</b>	<b>\$ 2,277</b>

<sup>1</sup> Average number of cases reported annually to DPH and confirmed as acute HCV, based on surveillance data from 2005 through 2009 (NC DPH data)

<sup>2</sup> 60% of all new/acute HCV cases can be attributed to injection drug use (CDC data)

<sup>3</sup> High-end estimate based on number of needle-sharing partners identified by persons with HIV who report injection drug use.

<sup>4</sup> Mean hourly wage for a Public Health Nurse II, obtained from the Public Health Nursing Program in the NC Division of Public Health.

<sup>5</sup> Hourly wage for a Public Health Nurse Consultant II, mid-range, Salary Grade 77, NC Office of State Personnel.

## APPENDIX

10A NCAC 41A.0214 is proposed for adoption as follows:

### 10A NCAC 41A .0214 - CONTROL MEASURES - HEPATITIS C

The following are the control measures for hepatitis C infection.

(1) Infected persons shall:

- (a) not share needles or syringes, or any other drug-related equipment, paraphernalia, or works that may be contaminated with blood through previous use;
- (b) not donate or sell blood, plasma, platelets, or other blood products.

(2) Persons with acute hepatitis C infection shall:

- (a) if the time of initial infection is known, identify to the local health director all needle partners since the date of infection; and, if the date of initial infection is unknown, identify persons who have been needle partners during the previous six months;

(3) The attending physician shall:

- (a) advise all patients known to be at high risk, including injection drug users, hemodialysis patients, patients who received blood transfusions or solid organ transplants before July 1992, patients who received clotting factor concentrates made before 1987, persons with HIV infection, and persons with known exposure to hepatitis C, that they should be tested for hepatitis C;
- (b) advise infected persons of the potential for transmission to others via blood or body fluids;
- (c) recommend that the infected patient seek medical evaluation for the presence or development of chronic liver disease;
- (d) recommend that hepatitis C chronic carriers receive hepatitis A and hepatitis B vaccines (if susceptible);

(4) When a health care worker or other person has a needlestick, non-intact skin, or mucous membrane exposure to blood or body fluids that would pose a significant risk of hepatitis C transmission if the source were infected with the hepatitis C virus, the following shall apply:

- (a) when the source is known, the source person shall be tested for hepatitis C infection, unless already known to be infected;
- (b) exposed persons shall be notified about the infection status of the source and advised to seek testing for Hepatitis C infection if the source person is infected with hepatitis C virus or the source person's infection status is unknown.

*History Note: Authority G.S. 130A-135; 130A-144.*